DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 13, 2015

Shenzhen Dongdixin Technology Co. Ltd.
Jianping Kang
M.R.
No.3 Building, XiLiBaimang Industrial Estate Nanshan District
Shenzhen, Guangdong, 518108 China

Re: [510(k) Number] K150436
Trade/Device Name: ComboRehab
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and Muscle Stimulator
Regulatory Class: Class II
Product Code: IMG, IPF, GZJ, GZI, LIH, HCC
Dated: February 10, 2015
Received: October 13, 2015

Dear Mr. Jianping Kang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S FDA

Carlos Peña, PhD, MS
Division Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150436

Device Name
ComboRehab

Indications for Use *(Describe)*
Therapeutic Ultrasound
Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:
1. Pain relief, muscle spasms and joint contractures.
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
• Adhesive capsulitis
• Bursitis with slight calcification
• Myositis
• Soft tissue injuries
• Shortened tendons due to past injuries and scar tissues
3. Relief of sub-chronic, chronic pain and joint contractures resulting from:
• Capsular tightness
• Capsular scarring

For TENS, Interferential, premodulated(IFC), NMS and Microcurrent:
1. Symptomatic relief of chronic intractable pain
2. Post-traumatic acute pain
3. Post-surgical acute pain

Additionally for NMS, NMS Burst, Hi-Volt and Russian:
1. Relaxation of Muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Maintaining or increasing range of motion
6. Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

For EMG
To determine the activation timing of muscles for:
1. Retaining of muscle activation
2. Coordination of muscle activation

An indication of the force produced by muscle for control and maintenance of muscle contractions
1. Relaxation muscle training
2. Muscle re-education

For EMG triggered Stim
1. Stroke rehab by muscle re-education
2. Relaxation of muscle spasms
3. Prevention or retardation of disuse atrophy
4. Increase local blood circulation
5. Muscle re-education
6. Maintaining or increasing range of motion

For DC Continuous Mode
Relaxation of muscle spasm

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

ComboRehab, K (150436)

Date of Prepared:	02/10/2015
Submitter's Name:	Shenzhen Dongdixin Technology Co., Ltd
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This 510(K) Summary of 510 (K) safety and effectiveness information is being submitted is being submitted in accordance with requirements of Title 21 CFR Section 807.92.

1. Proposed Device:

1.1. Device Trade Name: ComboRehab

1.2. Regulation numbers and common names:

a. 21 CFR 890.5850-Stimulator,Muscle ,Powered
b. 21 CFR 890.5860-Ultrasound and muscle stimulator
c. 21 CFR 882.5890-Transcutaneous electrical nerve stimulator for pain relief
d. 21 CFR 882.5050-Biofeedback device
e. 21 CFR 882.5810-External functional neuromuscular stimulator

1.3. Classification: Class II

1.4. Product Code: IMG, GZJ, GZI, IPF, LIH, HCC

2. Predicate Device:

2.1. Chattanooga Vectra Genisys -- K062354

2.2. CT1000 SonicStimu Combo -- K120217

3. Description of Proposed Device:

ComboRehab is four channels combination unit, can provide muscle stimulation, ultrasound, biofeedback and combination therapy. This product is designed to offer a multiple choices for clinician in one compact and integrated package.

A large control knobs located on the panel, allows clinician very easy to select different therapy mode and set therapeutic parameters. The award winning design offers a 5 inch Touch TFT LCD color display screen that can helps clinician to monitor the treatment information promptly.

In the electrotherapy mode, it's freedom for clinician to select one, two, three or four channels into therapy. A comprehensive set of current waveforms is available, targeting both pain management and muscle stimulation applications; interferential (4-pole), premodulated (2-pole interferential), Russian, NMS (Pulsed mode, burst mode), high volt, TENS, Microcurrent and Direct current.

The Ultrasound mode can be equipped with two applicators, 1cm^2 and 5cm^2. The applicators can operate in continuous or pulsed mode at an ultrasound frequency of 1 MHz or 3 MHz.

The EMG mode can provide us detail information about the organ-specific properties of a muscle through surface EMG electrodes. EMG biofeedback activity can couple with triggered electrical muscle stimulation using selected electrotherapy waveforms for the maximum benefit in muscle re-education.

The combination electrotherapy is used for the management of pain and muscle spasm. All functions of 1 or 3 MHz Ultrasound can be combined with Interferrential, Premodulated, Asymmetrical Biphasic, NMS, NMS burst mode, and High Voltage pulsed Current.

4. Proposed Device Intended Use Statement:

Therapeutic Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:

1) Pain relief, muscle spasms and joint contractures.
2) Relief of pain, muscle spasms and joint contractures that may be associated with:
   - Adhesive capsulitis
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   - Shortened tendons due to past injuries and scar tissues
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For EMG

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For EMG triggered Stim

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2) Relaxation of muscle spasms
3) Prevention or retardation of disuse atrophy
4) Increase local blood circulation
5) Muscle re-education
6) Maintaining or increasing range of motion

For DC Continuous Mode

1) Relaxation of muscle spasm

5. Technical and Performance Comparison

The following table compares the device to the predicate device with basic technological characteristics.

1	510K#	K	K120217	K062354
2	Device Name	ComboRehab	CT1000 SonicStimu Device	Vectra Genisys
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.	Shenzhen Dongdixin Technology Co., Ltd.	Chattanooga Group
4	Power Source	AC line	AC Line	AC line
	-Method of Line current isolation	Transformer	Transformer	Not stated in the Manual
	- Patient Leakage Current (μA) -Normal condition -Single fault condition	 d.c:0. a.c.:76.5 d.c:0. a.c.:132.1	 d.c:0. a.c.:78.9 d.c:0. a.c.:135.8	 Not stated in the Manual Not stated in the Manual
5	Number of Output Modes	10	10	10
6	Number of Output Channels	4	2	2
	Synchronous Or Alternating	N/A	N/A	1&2 or 3&4
7	Constant Current Constant Voltage	Optional Optional	Optional Optional	Optional Optional
8	Software/Firmware/Microprocesso Control	Yes	Yes	Yes
9	Automatic Overload Trip	Yes	Yes	Not Stated in the Manual
	Automatic Over Current Trip	Yes	Yes	Warning only, Overcurrent
10	Automatic No Load contact Trip	Yes	Yes	Warning only, Bad electrode contact
11	Automatic Shut off	Yes	Yes	Yes

12	Patient Override Control Method	Yes Patient interrupt switch	No ON/OFF, Hold or Stop	Yes Patient interrupt switch
13	Indicator Display			
	-On/Off Status	Yes	Yes	Yes
	-Voltage/Current Level?	Yes	Yes	Yes
	-Low Battery indicator	Yes	N/A	N/A
14	Timer Display	0-60 minutes	0-60 minutes	0-60 minutes
15	Standards	ISO14971, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC60601-2-5,MDD 93/42/EEC, Annex Ⅱ,	ISO14971, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC60601-2-5,MDD 93/42/EEC, Annex Ⅱ,	UL/IEC/EN 60601-1,IEC/EN 60601-1-2, IEC 60601-2-5, IEC 60601-2-10
16	Compliance with 21 CFR 898	Yes	Yes	Yes
17	Weight (lbs.)	10.36	3.0	7
18	Dimensions (in.) H*W * L	10*7x15.5	9.8*7.2*3.2	8.8*11.375*12.75
19	Housing Materials & Construction	Plastic	Plastic	Plastic

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

ComboRehab did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Nonclinical testing was performed in order to validate the design according with the company's specified design requirements, and to assure conformance with the following voluntary design standards:

- IEC 60601-1 " Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance".
- IEC 60601-1-2 " Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests"
- IEC 60601-2-10 " Medical Electrical Equipment -- Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators. (Neurology)s"
- IEC 60601-2-5 "Medical electrical equipment - Part 2-5: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Physiotherapy Equipment"
- IEC60601-2-40 “Medical electrical equipment - Part 2-40:Particular requirements for the safety of electromyographs and evoked response equipment”

7. Discussion of Clinical Tests Performed:

Not applicable

8. Conclusions:

The proposed device has the same intended use and similar characteristics as the predicate device, the CT1000 SonicStimu Device and Vectra Genisys. Moreover, bench testing, and safety repor documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device.

Thus, ComboRehab Device is substantially equivalent to the predicate device.